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MYERS BIG	EL SIBLEY & SAJO	BARKER, N	BARKER, MICHAEL P	
PO BOX 3742	8			
RALEIGH, NC 27627			ART UNIT	PAPER NUMBER
			1626	
				·

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	<u>.</u>	Application No.	Applicant(s)		
Office Action Summary		10/715,147	KING ET AL.		
		Examiner	Art Unit		
		Michael P. Barker	1626		
Period fo	The MAILING DATE of this communication app or Reply	pears on the cover sheet with the	correspondence address		
A SH WHIC - Exter after - If NO - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.11 SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period ver to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tire will apply and will expire SIX (6) MONTHS from to cause the application to become ABANDONE	N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133).		
Status					
2a)□	Responsive to communication(s) filed on <u>17 N</u> . This action is FINAL . 2b) This Since this application is in condition for alloward closed in accordance with the practice under Expression 1.	action is non-final. nce except for formal matters, pro			
Dispositi	on of Claims	·			
5)□ 6)□ 7)⊠	Claim(s) <u>1-24</u> is/are pending in the application. 4a) Of the above claim(s) <u>1-10 (in part) and 11-11.</u> Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) <u>1-10 (in part) and 11-24</u> is/are objected. Claim(s) <u>1-24</u> are subject to restriction and/or expressions.	- <u>24</u> is/are withdrawn from consident of the consident of	eration.		
Applicati	ion Papers				
10) <u> </u>	The specification is objected to by the Examine The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	epted or b) objected to by the drawing(s) be held in abeyance. Se tion is required if the drawing(s) is ob	ee 37 CFR 1.85(a). ojected to. See 37 CFR 1.121(d).		
Priority ι	ınder 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attach	*(a)				
2) Notice 3) Information	ce of References Cited (PTO-892) ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date 1/26/04.	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal I 6) Other:	y (PTO-413) Date Patent Application (PTO-152)		

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DETAILED ACTION

Claims 1-24 are pending in the instant application and are subject to a restriction requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 11-20 are drawn to compounds of Formula II,
$$R^{6}$$
 R^{7} R^{2} R^{7}

II. Claims 11-20 are drawn to compounds of Formula II, classified in various subclasses of classes 540, 544, 546, and 548.

III. Claims 21-24 are drawn to compounds of Formula III, R⁰ N R², coupled with methods of making compounds of Formula III, classified in various subclasses of classes 540, 544, 546, and 548.

Rationale Establishing Patentable Distinctiveness Within Each Group

Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention (Group) would be obvious over the other invention, i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures is not irrebuttable and may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of *Application of Papesch*, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and *In re Lalu*, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference

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anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103.

The above groups represent general areas wherein the inventions are independent and distinct, each from each other, because of the following reasons:

Groups I-III are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, as pointed out in the specification, the intermediate products are deemed to be useful as synthetic compounds for modulating nicotinic acetylcholine receptors; and, the inventions are deemed patentably distinct, since there is nothing on this record to show them to be obvious variants. Specifically, the compounds of Formulas II and III can be used to create variants of nicotine other than the Markush group listed in Claims 1-10.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission <u>may</u> be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The products of Groups I-III differ materially in structure and in element. Groups I-III, as outlined above, relate to a set of structurally diverse compounds, which together with their processes of preparation, do not possess a substantial common core wherein a reference

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anticipating one would render the other obvious. Thus, to search all of the above Groups in a single application would present an undue burden to the Examiner.

Further, Groups I-III are independent and distinct from each other, as they are drawn to compounds which have divergent moieties. Specifically, the compounds of Group I, drawn to compounds of Formula I, contain a carbonyl-containing group, whereas neither of the compounds of Groups II or III contain such a functional group. Moreover, Groups II and III vary from each other in the compounds of Formula III contain a hydroxyl group, where Group II, drawn to compounds of Formula III, does not.

For instance, Group II is distinct and independent from Groups I and III because it is directed to a different statutory class of invention, such that the practice of Group II would not result in the practice of Groups I or III. In addition, because of the numerous classes and subclasses in each of the Groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas.

Therefore, because of all of the reasons in the above paragraphs, the restriction set forth is proper where not restricting would result in a serious burden in the examination of this application.

Where an election of Groups I-III is made, an election of a single compound is further required including an exact definition of each substitution on the base molecule (Formulas I, II, and III), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R₁, wherein R₁ is recited to be any one of H or R, where R is selected from lower alkyl, alkenyl, alkynyl, or allenyl, or R₁, applicant must select a single substituent of R₁, for example H or R and each subsequent variable position.

In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound and the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination, as set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compound(s) and method(s) are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter.

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The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can set forth a group of compounds, which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and subclassifications, restriction for examination purposes, as indicated, is proper.

Applicants preserve their right to file a divisional application on the nonelected subject matter.

Advisory of Rejoinder

The following is a recitation of M.P.E.P. 821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

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Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance.

Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

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Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101,102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action. Form paragraphs 8.42 through 8.44 should be used to notify applicant of the rejoinder of process claims which depend from or otherwise include all the limitations of an allowable product claim.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.EP 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed

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proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

On September 26, 2005, a telephone call was made to Kenneth D. Sibley to request an election to the above restriction requirement, and a provisional election was made, *without* traverse, to prosecute the invention of **Group I**.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Response to Restriction

Applicant's election without traverse of Group I, Claims 1-10 (in part), drawn to

compounds represented by Formula I,

, and specific compound 1-[4-

(dimethylphenylsianyl)-3-(1-methylpyrrolidin-2-yl)-4H-pyridin-1-yl]-2,2-dimethylpropan-1-one,

, found in Example 1 on pp. 14-16 of the Specification, classified in subclass (314)+ of class 546, is acknowledged. Applicant's selected species is a compound of Formula I, wherein

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• R^4 is $SiR^{20}R^{21}R^{22}$, wherein R^{20} , R^{21} , and R^{22} are each alkyl (R^{20} =phenyl; R^{21} =methyl, R^{22} =methyl);

- R⁵ and R⁶ are hydrogen;
- R¹ is t-butyl;
- R⁷ is methyl;
- A is a 1 atom briding species which forms part of a saturated 5-membered ring including
 N⁷, C⁸, C⁹, and B; and
- **B*** is CH₂.

*Note: Applicant has NOT defined B, such that B could be a carbon-containing group. However, due to Applicant's selected species, Examiner is assuming Applicant intended to include amongst B's options a carbon-containing group or groups. Please amend accordingly in response to this Office Action.

The inventions of Groups I-III are each independent and distinct from each other because there is no patentable coaction between the Groups, and a reference anticipating one member will not render another obvious. Each Group is directed to art recognized as divergent in subject matter requiring different search strategies. Moreover, the Examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is burdensome to the Examiner. Thus, the restriction set forth September 26, 2005 is deemed proper.

As stated above in the restriction requirement, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound, and examination will then proceed on the elected compound and the entire scope of the invention encompassing the elected compound as defined by common classification.

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Regarding requests for rejoinder, as stated in the restriction requirement above, rejoinder will be permitted when a product claim is found allowable, and then the withdrawn process or methods claims which depend from or otherwise include all limitations of an allowed product claim will be rejoined.

Scope of the Invention of the Elected and Examined Subject Matter is as Follows

Compounds of Formula I,

, depicted in Claim 1, wherein:

- R⁴ is as defined;
- R¹ is alkyl, aryl, alkenyl, alkynyl, alkoxy, NR"₂, or SR", where R" is alkyl, aryl, alkenyl, alkynyl, or alkoxy;
- R², R⁵, and R⁶ are as defined;
- R⁷ is as defined;
- A is a 1, 2, or 3-atom bridging species which forms part of a saturated or monounsaturated 5-, 6-, or 7-membered ring including N⁷, C⁸, C⁹, and B.
- B^* is selected from CH_2 , O_1 , S_2 , or NR^{40} , or CR^{10} , wherein R^{10} is as defined; and
- R⁹ and R^{9A} are as defined.

The scope of Applicant's independent invention, set forth in Group I, encompasses all compounds within the scope of the claims of Group I which fall into the same class as the

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selected compound, , specifically class 546. All compounds falling outside the class of the selected compound are considered to be directed toward nonelected subject matter and are heretofore withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b).

Regarding the scope of the compounds set forth above, the compounds are free of the prior art as put forth above. Amendments to the claims in order to conform with the scope of compounds set forth above and cancellation of the nonelected subject matter will put Applicant's claimed invention in condition for allowance. Applicant has the right to file divisional applications on the remaining subject matter.

The closest prior art is U.S. Application No. 10/925,516, filed August 25, 2004, given priority to Provisional Application No. 60/497,826, filed August 26, 2003.

Scope of the Nonelected Subject Matter

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of Group I, Claims 1-10, which is not drawn to the above elected invention as well as Groups II and III, Claims 11-20 and Claims 21-24 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to nonelected inventions. The remaining compounds, which are not within the class of the elected invention, which are independent and distinct from the elected invention, and do not have unity with the elected compound, are therefore withdrawn by means of a restriction requirement within the claims. These claims include, for example, the compounds of Group I, Claim 1 wherein:

• \mathbf{R}^1 is alkoxy or $N\mathbf{R}^{"2}$;

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• A is a 3-atom bridging species which forms part of a saturated or monounsaturated 7membered ring including N⁷, C⁸, C⁹, and B; and

• **B** is selected from $-\Theta$. S, or $-NR^{10}$, wherein R^{10} is as defined.

The abovementioned withdrawn compounds and their corresponding methods, which are withdrawn from consideration as being nonelected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds contain varying functional groups which differ from those of the elected invention, such as morpholine, isooxazole, and thiazole, which are recognized to differ chemically in both structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 544 subclass (231.2)+ morpholine, class 548 subclass (240)+ isooxazole. Therefore, the compounds which are withdrawn from consideration as being nonelected subject matter differ materially in structure, function, and composition and have been restricted properly as a reference that anticipated, but the elected subject matter would not even render obvious the nonelected subject matter. The fields of search required for nonelected versus the elected compounds are not coextensive.

Priority

Applicant makes no claim for foreign or domestic priority. Therefore, the priority date given for this application is the filing date, November 17, 2003.

Information Disclosure Statement

Applicant's information disclosure statements (IDS), filed on January 26, 2004, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

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References Cited

If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicated the copy was not readily available, the copy could not be readily obtained when the Office action was mailed. Should Applicant desire a copy of such a provisional application, Applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 C.F.R 1.14(a)(1)(iv), paying the required fee under 37 C.F.R 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless Applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

Claim Objections

Claims 1-10 (in part) and 11-24 are objected to for containing nonelected subject matter.

Claim 1 is objected to for not including carbon-containing groups as options for B. Please amend Claim 1 in response to this Office Action. For further explanation, see the highlighted

*Note above, under the *Response to Restriction* heading.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

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When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is viable through Private PAIR only.

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For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center

(EBC) at 866-217-9197 (toll-free).

KAMAL A. SAEED, PH.D. PRIMARY EXAMINED

Michael P. Barker

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